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EXAMINER

FUBARA, BLESSING M

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,13,27-54,65-72,98,99,102,125-147,158-164,182-192,198,199 and 232-235.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 28-33,42-54,65,66,70,71,98,99,102,125-147,158-164,182-192,198 and 199.

DETAILED ACTION

The examiner acknowledges receipt of amendment to the claims, remarks and request for extension of time, all filed 10/30/08. Claims 20-26, 90-93, 114, 115, 118-124, 200-203, 236 and 237 are canceled. Claims 1, 2, 13, 27-54, 65-72, 98 are 39 are amended. Claims 28-33, 42-54, 65, 66, 70, 71, 98, 99, 102, 125-147, 158-164, 182-192, 198 and 199 and 233 are withdrawn from consideration. Claims 1, 2, 13, 27, 34-41, 67-69, 72 and 232 and claims 234 and 235 (in light of the amendment changing dependency of claim 234 to claim 69) are examined.

Claims 139, 142, 146, 147, 159, 164, 189, 191 and 198 were previously amended in the amendment filed 1/22/08. Thus, the status identifier, of "withdrawn" for these claims, does not tell the whole story and does not comply with the method of making amendment and listing of claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 2, 13, 27, 34-41, 67-69, 72 and 232 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (US 5,716,981) in view of Cooper et al. (US 5,962,007) and Datta et al. (US 6,338,739) for reasons of record with modification to account for the amendment to the claims.

4. Hunter discloses an anti-angiogenic composition in the form of a mesh (column 22, lines 51 and 52; column 26, lines 24-26), the mesh comprises anti-angiogenic compound and biodegradable carrier compound (column 3, lines 44-61), which is polyester, polymers and oligomers and copolymers of lactides and glycolides, such a polylactide, polyglycolides and lactide-glycolides or PLGA and blends thereof (column 16, lines 31-56). Example 28 uses paclitaxel as the therapeutic agent (Example 28). The device of claim 1 reads on the composition of Hunter. Hunter's mesh meets the requirements for mesh in claim 1 and since a mesh can either be woven, non-woven or knitted, it would be obvious to have the mesh woven or non-woven or knit and can be in the form of fabric; the requirement for a mesh fabric wrap in the claims is obvious over the teaching of a mesh that is capable of being formed into a wrap. The PLGA of Hunter (column 3, line 58; column 77, lines 54 and 55) reads on the polymer/biodegradable polymer of claims 1, 13, 27 making the mesh biodegradable. The mesh comprising the carrier and antiangiogenic agent, paclitaxel, meets the requirements of claims 234 and 235 except that Hunter is silent on the concentration of the paclitaxel per unit area of the

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mesh and the paclitaxel, an anti-proliferative agent resides within the fibers of the mesh meeting the requirements of claims 67-69. Example 28 also uses either PCL or PDLLA or PLGA and uses 50:50 PLGA (column 78, lines 21, 55). The composition of Hunter having the therapeutic agent, anti-angiogenic agent or paclitaxel has polymeric carrier, such as PLGA, MePEG-PLGA (column 18, line 35) with the MePEG-PLGA meeting the limitations of claims 34-37. Claim 72 recites the intended use or properties of the antiproliferative agent in the composition of claim 1 and since the composition of Hunter contains paclitaxel an anti-proliferative or anti-angiogenic agent, the composition is intrinsically capable of possessing these properties and is also capable of performing the intended use. Regarding claims 40 and 41, the artisan has good reason to use MePEG having molecular weight that would produce polymeric carrier desired for the anticipated delivery of the antineoplastic agents. Claim 232 recites the intended use of the composition of claim 1 such that the mesh product of Hunter in view of Copper and Datta would also be capable of being used as a perivascular wrap or used to wrap the blood vessel in the embolization process in the treatment of tumors.

However, the PLGA has 50:50 lactide and glycolide in Example 28 and Hunter does not teach a lactide glycolide ratio of 3:97 to about 15:85, in which the polymer has a higher percent of glycolide. However, Cooper discloses polymeric carrier, polyglycolide-co-lactide polymer having ratios of 95:5 to 5:95 for carrying varieties of different therapeutic agents such as antineoplastic agents (column 4, lines 7-10, 56). Furthermore, it is known in the art that biodegradable polymers such as PLGA, is faster degrading when the polymer is rich in glycolide, such as having at least 80 mole percent as evidence by column 3, lines 50-55; column 4, line 17). Therefore, taking the teachings of the references together, one having ordinary skill in the art at

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the time the invention was made would have reasonable expectation of success to modify the composition of Hunter by optimizing the monomer amounts of the glycolide and lactide to arrive at the anticipated delivery vehicle having the desired biodegradation for the delivery and release of the anti-angiogenic agent/anti-proliferative agent. The composition optimized for the amounts of lactide/glycolide meets the lactide rich polymer requirements of claims 1 and 38, 39. Therefore, absent a factual showing, percent glycolide rich polymers in the ranges recited is not inventing over the teachings of the prior art.

Response to Arguments

Applicant's arguments filed 10/30/08 have been fully considered but they are not persuasive. The examiner carefully considered the arguments as they relate to the amended claims and the interview held with the applicant on 6/03/08.

Applicant argues:

A) that Hunter does not mention biodegradable mesh fabric. The examiner agrees with applicant that Hunter does not use the phrase "biodegradable mesh fabric." However, Hunter teaches composition in the form of a mesh and a mesh can either be woven, non-woven or knitted and in the form of fabric. The fact or idea that a mesh can be woven or non woven fabric is supported by applicant when the instant specification is gleaned as dictionary for the meaning of mesh fabric as found in paragraph [0099] of the published application. Furthermore, because the mesh of Hunter comprises biodegradable polyester, it flows that the mesh comprising the angiogenic composition is biodegradable.

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Applicant has also stated that the mesh of Hunter is of a tubular configuration into which the stent may be inserted and that the mesh is not in the form of a sheet of fabric. The examiner agrees with applicant that the stent is tubular and in the embodiment where the stent is inserted into the mesh, the mesh is tubular. But claim 1 is directed to a product or composition and the composition of Hunter is in the form of a mesh, which can either be woven or non woven fabric as described above. The limitation of the mesh being a wrap or capable of being wrapped reads on any mesh that is a fabric and being a fabric mesh, it can intrinsically be capable of being wrapped around a target and specifically, the broad wrap is interpretable as a coating that wraps the stent keeping in mind that the mesh comprises biodegradable polymer and therapeutic agent. The term wrap is also the intended use of the composition that is fully defined in the body of the claim as comprising biodegradable polymer and therapeutic agent. The composition of Hunter is also capable of being used as a wrap depending on the target upon which the composition is applied. For example, one would not use a stent in a topical application making it obvious to use the mesh as a wrap.

B) that Hunter does not teach the specific range of lactide:glycolide ratio. Yes, the examiner agrees that Hunter does not teach the specific ratio recited in the claims and that is why the rejection is not an anticipatory one. Further, it is known in the art that PLGA rich in glycolide degrades faster (see column 3, lines 50-55, column 4, lines 17-21 of Datta) so that if the goal of is to have a fast degrading composition, then the artisan would be motivated to use PLGA polymers having high amounts of glycolide noting that these PLGA copolymers have specified percents of lactide and glycolides. Regarding claim 2, it is presented above that the mesh is woven or non-woven or knit and can be in the form of fabric. Regarding claim 13, it is

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noted that a disclosure for PLGA without specifying L- or D- lactide:glycolide, indicates that both forms are present in the generic PLGA and there is no demonstration the L-lactide-co-glycolide provides unexpected results to the composition. For claims 38 and 39, the ratio of MePEG:polyester workable in the composition of Hunter can be ascertained by the artisan and is also noted that the rejection is not one of anticipation but one where the claimed invention would be obvious over the combination of the references. In the absence of factual evidence, the claimed ratios in claims 38 and 39 is not inventive over the disclosed composition of the prior art.

C) that Cooper is directed to the deployment of medical construct. But, while that may be so, Cooper was not relied upon for teaching medical construct that is deployable, but was relied upon for teaching that PLGA polymers having 95:5 to 5:95 poly(glycolide-co-lactide) are effective delivery vehicles for antineoplastic agents (column 4, lines 7-10, 56).

D) that Datta relates to biodegradable stents for implantation. But while that may be so, Datta was not relied upon for implantation of biodegradable stent, but was relied upon for teaching that PLGA polymers having higher amounts of glycolide than the lactide component degrades faster.

Therefore, even for the sake of argument, the artisan would look to Cooper for a teaching that poly(glycolide-co-lactide) in ratio of 95:5 to 5:95 is effective delivery vehicles for antineoplastic agents, the artisan would also look to Datta for faster degrading PLGA in which the amounts of the glycolide is higher than the amount of lactide so that the artisan would be motivated to use PLGA having higher glycolide amounts relative to the lactide if the goal is a faster degrading PLGA. Therefore, claim 1 and the claims dependent thereon are rendered

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obvious by Hunter in view of Cooper and Datta; the claimed invention would have been obvious in light of the combination of the teachings of these references as described in the rejections and in the response to applicant's arguments.

Claims 1, 26 and 34-41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (US 5,716,981) in view of Cooper et al. (US 5,962,007) and Datta et al. (US 6,338,739) and further in view of Zhang et al. ("Development of amphiphilic diblock copolymers as micellar carries of taxol," in International Journal of Pharmaceutics 132:195-206, 1996, pp. 195-206, provided by applicant on 11/27/07 on PTO form 1449) for reasons of record and reiterated herein below.

The teachings of Hunter, Cooper and Datta are described above as rendering claim 1 obvious when the teachings of the references are taken together. While the ordinary skilled artisan has ordinary capabilities of using methoxy PEG having appropriate molecular weight for the methoxy PEG:polyester polymer in ratios appropriate to produce desired delivery carrier polymer, the prior art does not specifically teach the limitations of claims 38-41. But Zhang teaches that the molecular weight of the MePEG and the weight ratio of the PDLA and MePEG influence the ability of the polymer in solubilizing taxol (3rd full paragraph of page 126). Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that taking the teachings of the references together, modification of the polymer in view of the teachings of Zhang would lead to composition that would give the desired solubility of paclitaxel, which is a taxol.

Response to Arguments

Applicant's arguments filed 10/30/08 have been fully considered but they are not persuasive. The examiner carefully considered the arguments as they relate to the amended claims and the interview held with the applicant on 6/03/08

E) Applicant argues that Zhang does not make up for the deficiencies of Hunter, Cooper and Datta since Zhang is silent with respect to mesh fabric wraps and PLGA as mesh materials. The examiner disagrees with applicant's premise for traversing the rejections. Hunter teaches PLGA mesh. A mesh is woven, non woven, knit of fabric as stated in the rejections above and supported by applicant's specification used as a dictionary for the meaning of fabric/mesh (see paragraph [0099] of the published application. Zhang was relied upon for teaching that the molecular weight of the MePEG and the weight ratio of the PDLLA and MePEG influence the ability of the polymer in solubilizing taxol (3rd full paragraph of page 126), which is antineoplastic agent, so that the artisan would be mindful of the amounts of MePEG relative to PLGA or polyester needed for effective solubilization of antineoplastic agents.

Claims 1 and 232 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (US 5,716,981) in view of Cooper et al. (US 5,962,007) and Datta et al. (US 6,338,739) and further in view of Schrayner (US 6,575,887) for reasons of record and reiterated herein below.

Claim 1 is described above as rendered obvious by the combined teachings of Hunter, Cooper and Datta. Claim 232 recites the intended use of the composition of claim 1 such that the mesh product of Hunter in view of Cooper and Datta would also be capable of being used as a perivascular wrap or used to wrap the blood vessel in the embolization process. But, one of

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the goals of hunter is the embolization of blood vessels in the treatment of tumors using the paclitaxel containing composition (abstract; column 4, lines 14-19). Schrayner teaches wrapping blood vessels to mitigate overexuberant cellular proliferation (abstract; column 1, lines 8-12; column 4, lines 22-36). Therefore, one having ordinary skill in the art the time the invention was made would have reasonable expectation that wrapping the blood vessels in diseased tumor or cancer conditions would successfully mitigate proliferating cellular conditions.

Response to Arguments

Applicant's arguments filed 10/30/2008 have been fully considered but they are not persuasive.

F) Applicant argues that Schrayner is concerned with surgically implanting radioactive wraps that may be used to mitigate over-exuberant cellular proliferation and that the unintended consequences of delivery of paclitaxel to healthy tissues cannot be avoided by attenuating the radiation element. This is not persuasive. Schrayner is relied upon for teaching that over active cells of blood vessels can be treated by wrapping with a treatment device. In the same manner the mesh/fabric of Hunter can be used as a wrap around blood vessels to mitigate proliferating cellular conditions.

Claims 234 and 235:

Claims 234 and 235 dependent on withdrawn claim 233 and were therefore withdrawn from consideration in the office action of 4/30/08. It was however noted that claims 234 and

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235 which are directed to paclitaxel are also rejectable. The amendment to these claims correcting the dependencies of these claims gives rise to the rejection below.

Claims 1, 67, 69, 234 and 235 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (US 5,716,981) in view of Cooper et al. (US 5,962,007) and Datta et al. (US 6,338,739).

Hunter in view of Cooper and Datta has been described above to render obvious claims 1, 67 and 69. While the mesh of Hunter comprises polymer carrier and anti-angiogenic agent, paclitaxel, and meets the requirements of claims 234 and 235 and the anti-proliferative agent that resides within the fibers of the mesh meeting the requirements of claims 67-69, Hunter is silent on the concentration of the paclitaxel per unit area of the mesh. But the artisan has the technical skills of using paclitaxel in amounts that would lead to the desired treatment. Therefore, taking the teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation that specific amounts of paclitaxel relative to the area of the mesh can be optimized for use that would lead to the expected treatment effect of the anti-neoplastic.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

1. This application contains claims 28-33, 42-54, 65, 66, 70, 71, 98, 99, 102, 125-147, 158-164, 182-192, 198 and 199 drawn to an invention nonelected with traverse in the reply filed on 10/26/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Michael G. Hartley/
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